UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCIATION *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.[1]	Case No. 1:23-cv-00707

DEFENDANTS' COMBINED CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

ERIC J. HAMILTON
Deputy Assistant Attorney General

MARGARET LEACHMAN
Acting United States Attorney

MICHELLE R. BENNETT
Assistant Branch Director

STEPHEN M. PEZZI
Senior Trial Counsel
CASSANDRA M. SNYDER
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch

Counsel for Defendants

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Robert F. Kennedy, Jr., Secretary of Health and Human Services, is automatically substituted as a defendant in his official capacity for his predecessor, Xavier Becerra. Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, is likewise automatically substituted as a defendant in his official capacity for his predecessor, Chiquita Brooks-Lasure.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

U.S. Constitution

Statutes

Rules

Legislative Materials

Administrative and Executive Materials

Other Authorities

INTRODUCTION

For more than 30 years, Congress has limited how much federal agencies will pay for prescription drugs. Manufacturers that wish to sell their drugs to the Departments of Defense and Veterans Affairs, for example, do so subject to statutorily defined ceiling prices, and both agencies have authority to negotiate prices below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). In the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (IRA), Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices that Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. *See* 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the IRA's Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) can now negotiate the prices that Medicare will pay for a select group of drugs manufactured by companies that choose to sell drugs to Medicare and Medicaid.

Plaintiffs' lead argument is that the statute violates the nondelegation doctrine. But for 90 years, the Supreme Court has consistently upheld "Congress' ability to delegate power under broad standards," *Mistretta v. United States*, 488 U.S. 361, 373 (1989), and "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law,'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474-75 (2001) (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)). The "intelligible principle" test that governs this claim—though it goes unmentioned in Plaintiffs' brief—is "not demanding." *Gundy v. United States*, 588 U.S. 128, 145-46 (2019) (plurality op.). Plaintiffs are free to preserve this argument for further review, but under binding precedent, there is nothing particularly special about this statute that warrants finding a once-in-a-century violation of the nondelegation doctrine.

As to Plaintiffs' Eighth Amendment challenge to the IRA's excise tax, the Court should dismiss that claim for lack of subject-matter jurisdiction, as two other district courts have done. *See Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 23-cv-01103, 2024 WL 3292657, at *22 (D. Conn. July 3, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 23-cv-14221, 2024 WL 4524357, at *3 (D.N.J. Oct. 18, 2024). The claim is not redressable—and Plaintiffs therefore lacks Article III standing to assert it—

because no defendant in this lawsuit is empowered to enforce the tax that Plaintiffs seek to enjoin and have declared unconstitutional. Plaintiffs' claim is also barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), which prohibits any "suit for the purpose of restraining the assessment or collection of any tax," and by the tax exception to the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201(a), which prohibits issuance of declaratory judgments "with respect to Federal taxes." For both AIA and DJA purposes, a "tax" is an exaction that Congress has labeled as such, and Congress has unambiguously described the section 5000D excise tax as a "tax."

The tax claim would also fail on the merits. The excise tax does not violate the Eighth Amendment because it is neither a "fine" nor "excessive." Neither the Supreme Court nor, to Defendants' knowledge, any other court has ever held that a tax—let alone one that, like the one here, lacks any connection to a criminal offense—was a fine for Excessive Fines Clause purposes. Even if the tax were deemed a fine, it would not be a grossly disproportionate one, as the tax is proportional to the harm to the fisc and within the range of other constitutionally permissible exactions.

Finally, Plaintiffs' due process theory also fails. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *Am. Mfrs. Mut. Ins. v. Sullivan*, 526 U.S. 40, 59 (1999). Plaintiffs' due process claim thus doesn't even get off the ground, because drug manufacturers have no constitutionally protected property interest in their desire to continue selling their goods to the government at their preferred price.

BACKGROUND

I. Medicare and the IRA's Drug Negotiation Program

A. Congress created Medicare in 1965. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, 79 Stat. 286, 290-353. Medicare is a federal program that pays for covered healthcare items and services, including prescription drugs, for qualified beneficiaries. *See generally* 42 U.S.C. § 1395 *et seq.* The Medicare statute encompasses several "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

"Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and

laboratory services," as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq*. Prior to the IRA, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

This model has contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 36 (May 2021), https://perma.cc/9L42-VRBK. For example, manufacturers of brand-name drugs often fend off generic competitors by introducing inconsequential changes to their drug and shifting patients to that new version, a strategy known as "product hopping." H.R. Rep. No. 116-695, at 3 (2020). Similarly, brand-name manufacturers often protect their market share by entering into "settlements" with generic manufacturers that permit the generic to be marketed only nominally, without resulting in meaningful competition. *See, e.g.*, Sarah M.E. Gabriele, et al., *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 330 JAMA 1223 (2023). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June

2022), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to Medicare, undermining the program's premise of using market competition to reduce prices for beneficiaries and costs for taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under Part D, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. *See* Pub. L. No. 117-169, §§ 11001-11003 (codified at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through CMS, to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. § 1320f *et seq.* The Negotiation Program applies only to the prices Medicare pays for selected drugs that it covers; the statute regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of "negotiation-eligible drug[s]" from a set of "qualifying single source drugs." 42 U.S.C. § 1320f-1(d)–(e) (defining "negotiation-eligible drug" and "qualifying single source drug"). Congress directed CMS to select up to 10 such drugs for negotiation for initial price applicability year 2026, up to 15 drugs for initial price applicability years 2027 and 2028, and up to 20 drugs for initial price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)–(b).

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. In formulating offers during the course of those negotiations, the statute requires CMS to consider several categories of information, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings for the American people, Congress imposed a "[c]eiling

for [the] maximum fair price," which it tied to specified pricing data. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept. *Id.* § 1320f-3(b)(1).

CMS is directed to sign agreements to negotiate prices for selected drugs with willing manufacturers. *See id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to establish the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling the selected drug to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. *See* 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* Medicare Drug Price Negotiation Program: Revised Guidance 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Or it can withdraw from Medicare and Medicaid—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 120-21, 129-31; *see also* Pub. L. No. 117-169, § 11003 (codified at 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those Congress has long attached to other government healthcare programs. For example, Congress has long required that any drug manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs giving the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). As in those statutes, the Negotiation Program gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. CMS's Implementation of the Negotiation Program

Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, Medicare Drug Price

Negotiation Program: Initial Memorandum (Mar. 15, 2023), https://perma.cc/8X4K-CVD8 (Initial Guidance). After considering more than 7,500 public comments "representing a wide range of views," CMS published Revised Guidance on June 30, 2023. Revised Guidance at 1-2. The Revised Guidance applies only to initial price applicability year 2026. *See id.*

The Revised Guidance describes several aspects of CMS's implementation of the first year of the Negotiation Program, including the methodologies by which CMS selects drugs for negotiation, the negotiation process, the types of data that CMS considers in making an offer, and the procedures for manufacturers to follow if they decide not to participate in the Negotiation Program. *Id.* at 2-8. As to that last point, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33-34. The Revised Guidance also notes that manufacturers that wish to remain in the Medicare and Medicaid programs but that do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131–32.

The Internal Revenue Service (IRS) has separately explained how it interprets the IRA's excise-tax provision. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice). The Department of the Treasury, of which the IRS is a part, is charged with enforcing section 5000D and interpreting its provisions. *See* § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance . . . ."); *see also* 26 U.S.C. § 7701(a)(11)(B) ("When used in this title, . . . [unless otherwise stated], [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."). Under this authority, the Department of Treasury and the IRS have published several notices and regulations implementing the section 5000D tax: In August 2023, the IRS issued a notice announcing Treasury's intent to issue regulations implementing the section 5000D tax and providing taxpayers interim guidance on substantive and procedural issues related to the tax. *See* IRS Notice. In July 2024, after notice and comment, Treasury published a final rule setting forth procedural requirements related to the tax. *Excise Tax on Designated Drugs; Procedural Requirements*, 89

Fed. Reg. 55507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47). Most recently, in January 2025, Treasury published a notice of proposed rulemaking consistent with the agency's substantive interpretations of the tax as described in the 2023 Notice. *Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025).

On August 29, 2023, CMS published the list of drugs selected for negotiation for initial price applicability year 2026. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The drugs selected accounted for more than $50 billion—or about 20%—of gross Medicare Part D spending between June 2022 and May 2023. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94.

Manufacturers of selected drugs have challenged the constitutionality of the Negotiation Program in cases that are pending around the country.[2] To date, four district court judges have considered such constitutional claims on the merits, and each has rejected the claims. *See AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024) (Connolly, C.J.); *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440 (S.D. Ohio 2023) (Newman, J.); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-01103, 2024 WL 3292657 (D. Conn. July 3, 2024) (Shea, J.), *appeal filed*, No. 24-2092 (2d Cir Aug. 8, 2024); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) (Quraishi, J.), *appeals filed*, Nos. 24-1820 & 24-1821 (3d Cir. May 6, 2024); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024) (Quraishi, J.), *appeal filed*, No. 24-2510 (3d Cir. Aug. 19 2024); *Novartis Pharms. Corp. v. Becerra*, No. 23-14221, 2024 WL 4524357, at *2 (D.N.J. Oct. 18, 2024) (Quraishi, J.).

---

[2] *See Merck & Co. v. Kennedy*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio June 9, 2023); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. June 16, 2023); *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. July 18, 2023); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn. July 3, 2024); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. Aug. 25, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Sept. 1, 2023); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. Sept. 9, 2023); *Teva Pharms. USA, Inc. v. Kennedy*, No. 1:25-cv-113 (D.D.C. Jan. 15, 2025).

Plaintiffs here are not drug manufacturers. Rather, Plaintiffs include the National Infusion Center Association ("NICA"), a trade association of providers that "operate outpatient facilities to administer" infusion treatments and "receiv[e] reimbursement from Medicare for services provided to Medicare patients," Compl. ¶¶ 20-21; the Global Colon Cancer Association ("GCCA"), an organization that represents colon cancer patients, *id.* ¶ 22; and PhRMA, a trade association for "research-based pharmaceutical and biotechnology companies," *id.* ¶ 23.

For the first negotiation cycle, manufacturers of all the selected drugs executed agreements to negotiate the price of their respective drugs. *See* CMS, *Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE (*Manufacturer Agreements*). In accordance with the schedule established by Congress, CMS presented the drug manufacturers of selected drugs with initial offers by February 1, 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. Each participating manufacturer responded with a counteroffer by March 2, 2024. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright, and reached agreement with a fifth manufacturer on a negotiated price. *Id.*; *see also* Ex. 1, Buchmueller Decl. ¶¶ 20-23.[3] CMS then sent final written offers to manufacturers of the five remaining drugs. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. Assuming that none of the 10 manufacturers withdraw from

[3] Defendants respectfully maintain their position that expert witnesses are not necessary to decide this case, and that the Garthwaite Declaration should thus be excluded. *See* Defs.' Mot. to Exclude, ECF No. 61. Nevertheless, because Defendants' motion to exclude was denied, ECF No. 67, Defendants have now retained their own expert to respond to Professor Garthwaite's opinions about the leverage retained by CMS and drug manufacturers during price negotiations. That declaration is attached to this filing as Exhibit 1.

Medicare and Medicaid by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

Earlier this year, CMS announced the list of selected drugs for the second negotiation cycle. CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), *available at* https://tinyurl.com/5h7aka7x. Those negotiations have not yet begun.

III. Litigation Background

This case returns to this Court following a remand from the Fifth Circuit. On June 21, 2023, Plaintiffs brought a facial constitutional challenge to the portions of the IRA that create the Negotiation Program, asserting that these provisions violate (1) the nondelegation doctrine, Compl. ¶¶ 130-34; (2) the Excessive Fines Clause of the Eighth Amendment, *id.* ¶¶ 136-41; and (3) the Due Process Clause of the Fifth Amendment, *id.* ¶¶ 143-48.

On February 12, 2024, this Court granted Defendants' motion to dismiss. *See* Order Granting Defs.' Mot. to Dismiss at 1, ECF No. 53. The Court held that the Medicare Act's channeling provision deprived it of subject-matter jurisdiction to address Plaintiff NICA's claims, and that venue was thus improper. *See id.* at 12-13. On September 20, 2024, the Fifth Circuit reversed and remanded for further proceedings, holding that Plaintiff NICA had adequately alleged Article III standing, and that channeling under the Medicare Act was not required. *See Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 509 (5th Cir. 2024) (*NICA*).

ARGUMENT

I. Plaintiff's nondelegation claim is meritless.

Plaintiffs' lead argument is that the statutory provisions creating the Negotiation Program violate the nondelegation doctrine. But tellingly, the phrase "intelligible principle" does not appear once in Plaintiffs' brief—even though it is black-letter law that the "intelligible principle" test governs this claim, per a century of precedent from both the Supreme Court and the Fifth Circuit. *See, e.g.*, *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020). Applying that test, Plaintiffs' claim fails.

1. Article I provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1. Congress may not delegate those powers to the other branches of the government. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388, 421 (1935). Congress may, however, seek "assistance from another branch." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928). In particular, it may authorize executive agencies to exercise "discretion" in implementing and enforcing the laws that Congress enacts. *Id.*; *see, e.g.*, *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024) ("In a case involving an agency, of course, the statute's meaning may well be that the agency is authorized to exercise a degree of discretion."); *Wayman v. Southard*, 23 U.S. 1, 22 (1825) (Marshall, C.J.) ("[T]he maker of the law may commit something to the discretion of the other departments.").

If a statute sets forth an "intelligible principle" to guide the agency, it effects a lawful grant of discretion rather than an unlawful delegation of legislative power. *J.W. Hampton*, 276 U.S. at 409. A statute satisfies that requirement if it defines "the general policy" that the agency must pursue and "the boundaries of th[e] delegated authority." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). That test is "not demanding." *Gundy v. United States*, 588 U.S. 128, 146 (2019) (plurality op.).

Although Congress has delegated authority "from the beginning of the government," *Big Time Vapes*, 963 F.3d at 442 (quoting *United States v. Grimaud*, 220 U.S. 506, 517 (1911)), "[o]n only two occasions has the Court invalidated legislation based on the nondelegation doctrine, and both occurred in 1935," *United States v. Cooper*, 750 F.3d 263, 268 (3d Cir. 2014). One of those statutory provisions "provided literally no guidance for the exercise of discretion," and the other "conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (citing *Panama Refining*, 293 U.S. at 388; *Schechter Poultry*, 295 U.S. at 495).

By contrast, in the 90 years since, the Supreme Court has consistently upheld "Congress' ability to delegate power under broad standards," *Mistretta*, 488 U.S. at 373, and "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be

left to those executing or applying the law,'" *Am. Trucking*, 531 U.S. at 474-75 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)). For example, it has upheld laws that authorize agencies to:

- Regulate in the "public interest." *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943) (broadcast licensing); *United States v. Rock Royal Co-op, Inc.*, 307 U.S. 533, 576-77 (1939) (milk prices); *N.Y. Cent. Sec. Corp. v. United States*, 287 U.S. 12, 24-25 (1932) (railroad acquisitions).

- Prohibit "unreasonable" obstructions to the free navigation of navigable waters. *Union Bridge Co. v. United States*, 204 U.S. 364, 387 (1907).

- Raise the minimum wage "as rapidly as is economically feasible without substantially curtailing employment." *Opp Cotton Mills, Inc. v. Administrator*, 312 U.S. 126, 142-46 (1941).

- Set "just and reasonable" rates for natural gas. *FPC v. Hope Natural Gas Co.*, 320 U.S. 591, 600 (1944).

- Set "fair and equitable" commodity prices. *Yakus v. United States*, 321 U.S. 414, 420-27 (1944).

- Prohibit corporate structures that "unfairly or inequitably distribute voting power among security holders" in holding companies. *Am. Power & Light*, 329 U.S. at 104-06.

- Determine and recover "excessive profits" from military contractors. *Lichter v. United States*, 334 U.S. 742, 774-87 (1948).

- Set air-quality standards that are "requisite to protect the public health." *Am. Trucking*, 531 U.S. at 472-76.

Ultimately, modern nondelegation "jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." *Mistretta*, 488 U.S. at 372. The Constitution allows "Congress to obtain the assistance of its coordinate Branches," and to "confer substantial discretion on executive agencies to implement and enforce the laws." *Gundy*, 588 U.S. at 135 (plurality op.).

2. The IRA fits comfortably within these precedents. At the outset, Congress itself "made virtually every legislative determination" in creating the Negotiation Program, "which has the effect of constricting the [agency's] discretion to a narrow and defined category." *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009). Congress defined the critical terms. *See* 42 U.S.C. § 1320f(b), (c). Congress established detailed criteria for the selection of negotiation-eligible drugs and selected drugs. *See id.* § 1320f-1. Congress established multiple mathematical formulae for calculating ceiling prices.

See id. § 1320f-3(c). Congress specified the procedures for negotiation, down to specific timing deadlines that vary across different price applicability years. *See id.* § 1320f-3. And Congress established detailed parameters for agreements with participating manufacturers. *See id.* § 1320f-2.

Having resolved these minutiae (and many more) itself, Congress then (1) delegated to CMS the task of representing the government in negotiations, *id.* § 1320f-3(a), (2) directed it to "aim[] to achieve the lowest maximum fair price for each selected drug" for which it is able to persuade manufacturers to sign an agreement, *id.* § 1320f-3(b)(1), and (3) specified detailed criteria that CMS "shall consider" in "determining the offers and counteroffers" during the negotiation, up to the congressionally specified ceiling price, using data "submitted by the manufacturer":

> (A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.
>
> (B) Current unit costs of production and distribution of the drug.
>
> (C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
>
> (D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under [the Food Drug and Cosmetic Act].
>
> (E) Market data and revenue and sales volume data for the drug in the United States.

Id. § 1320f-3(e)(1). Congress also mandated consideration in determining offers and counteroffers of "evidence" about "therapeutic alternatives to such drug":

> (A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.
>
> (B) Prescribing information approved by the [FDA] for such drug and therapeutic alternatives to such drug.
>
> (C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

> (D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Id. § 1320f-3(e)(2).[4] That is more than enough. Indeed, Congress used far more detail here than in dozens of statutes that have been upheld in the face of nondelegation challenges in the past century. *See, e.g.*, *Am. Trucking*, 531 U.S. at 472 ("protect the public health"); *Nat'l Broad.*, 319 U.S. at 225-26 ("public interest, convenience, or necessity"). Especially in the context of a delegation governing the negotiation of individual contracts—a traditional Executive Branch function—no further detail was necessary. *See, e.g.*, *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (recognizing "the traditional principle of [Congress] leaving purchases necessary to the operation of our Government to administration by the executive branch of Government, with adequate range of discretion free from vexatious and dilatory restraints at the suits of prospective or potential sellers").

On Plaintiffs' telling, the agency "can decree any price it wants for a manufacturer's drug." Pls.' Mot. for Summ. J. 2, ECF No. 60 (Pls.' Br.). That unexplained accusation simply ignores the detailed criteria above—which is why Plaintiffs walk it back later in their brief, retreating to the narrower claim that Congress was somehow supposed to provide more "guidance on how to weigh those factors" and that these conceded statutory constraints are insufficiently "concrete." *Id.* at 17. But because Congress defined both "the general policy" that the agency must pursue and "the boundaries of th[e] delegated authority," *Am. Power & Light*, 329 U.S. at 105, no further guidance was required.

Plaintiffs also acknowledge, as they must, that the statute *does* provide detailed and prescriptive mathematical formulae setting "a minimum discounted 'ceiling' price," and then also instructs the Secretary to "achieve the lowest maximum fair price" that a manufacturer will accept. Pls.' Br. at 17 (citing 42 U.S.C. § 1320f–3(b)(1), (c), (e)) (emphasis omitted). But Plaintiffs never even try to explain

---

[4] Congress also specified that, "[i]n using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." 42 U.S.C. § 1320f-3(e)(2)(D).

why *those* limitations are insufficient (either standing alone, or in conjunction with the detailed criteria above). Of course, for policy reasons, Plaintiffs would undoubtedly prefer a statute with mathematical formulae setting a high *floor* price instead of a high *ceiling* price. And they likewise wish Congress directed the agency to pursue the *highest* price that a manufacturer will accept, rather than the *lowest*. But the nondelegation doctrine requires only an intelligible principle, and the provision of a ceiling price coupled with detailed criteria for the agency's offers and counteroffers easily meets that standard.

3. All but ignoring the intelligible-principle test, Plaintiffs instead throw a variety of largely unrelated statutory features into a soup, on the theory that "two or more things that are not independently unconstitutional *can combine* to violate the Constitution's separation of powers." Pls.' Br. at 15 (quoting *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (en banc), *cert. granted*, 145 S. Ct. 587 (2024)). But Plaintiffs' gerrymandered legal theory—which posits that a collection of otherwise unremarkable statutory features together "epitomize[] an unconstitutional delegation," Pls.' Br. at 15—finds no support in either Supreme Court or Fifth Circuit precedent.

Primarily, Plaintiffs lament that (in their words) "the IRA purportedly *eliminates* judicial review of critical administrative decisions." *Id.* (quoting 42 U.S.C. § 1320f-7). But limitations on judicial review—routine in the Medicare context, *see infra* at 16—have no obvious logical connection to the operative question under the nondelegation doctrine: whether Congress provided an intelligible principle to guide agency discretion. There is no substance to Plaintiffs' suggestion that Congress had to vest more power in *courts* to avoid a conclusion that it surrendered too much of its own power to the Executive Branch. The Constitution's vesting of legislative power in Congress does not also require litigation over the agency's offer price, with the final say about the "maximum fair price" of complex pharmaceuticals to be made by federal judges. Ultimately, it is thus Plaintiffs' proposal that would "avoid accountability," Pls.' Br. at 1—after all, unlike the courts, the Secretary of Health and Human Services is directly accountable to an elected President.

Although Plaintiffs cite (at 42) out-of-circuit dicta for the theory that the *availability* of "judicial review is a factor weighing in favor of *upholding* a statute against a nondelegation challenge," *United States v. Garfinkel*, 29 F.3d 451, 458-59 (8th Cir. 1994) (emphasis added), they cite no case holding that

preclusion of judicial review creates a nondelegation problem, and Defendants are aware of no such case. At least one holds the opposite. *See United States v. Bozarov*, 974 F.2d 1037, 1045 (9th Cir. 1992) ("[T]he EAA's preclusion of judicial review does not violate the nondelegation doctrine."). That is unsurprising: the nondelegation doctrine is about the power that Congress has delegated to the Executive Branch, on the front end—not whether the exercise of that power is subject to judicial review, on the back end.[5]

Indeed, Plaintiffs' theory that preclusion of review creates a delegation problem is inconsistent with another line of settled precedent—which holds that, at least within outer bounds not relevant here,[6] Congress's "control over the jurisdiction of the federal courts is plenary." *Patchak v. Zinke*, 583 U.S. 244, 252 (2018) (citation omitted). Because Congress alone "possess[es] the sole power of creating the tribunals (inferior to the Supreme Court)," it also has the exclusive power "of withholding jurisdiction from them in the exact degrees and character which to Congress may seem proper for the public good." *Palmore v. United States*, 411 U.S. 389, 401 (1973) (quoting *Cary v. Curtis*, 44 U.S. 236, 245 (1845)); *accord Kontrick v. Ryan*, 540 U.S. 443, 452 (2004) ("Only Congress may determine a lower federal court's subject-matter jurisdiction." (citing U.S. Const. art. III, § 1)). Ultimately, when Congress limits federal jurisdiction, "it exercises a valid legislative power no less than when it lays taxes, coins money,

[5] Contrary to Plaintiffs' suggestion (at 14), *Touby v. United States*, 500 U.S. 160 (1991), is not to the contrary. There, the relevant statute *did* allow for judicial review, *see id.* at 168-69, so the Court did not have to (and did not) say whether the nondelegation doctrine required that result. Plaintiffs' citation (at 14) to Justice Marshall's concurrence proves the point—he (and Justice Blackmun) would have gone further, but that opinion attracted only two votes. *See id.* at 169-70 (Marshall, J., concurring). Plaintiffs' reliance (at 14) on *Consumers' Research* is likewise unavailing, as the problem there (according to the Fifth Circuit) was that a delegation that was "so amorphous that no reviewing court could ever possibly invalidate any [agency] action," 109 F.4th at 767, was coupled with a further delegation to private entities, *id.* at 778. Moreover, as in *Touby*, the statute at issue in *Consumers' Research* allowed for judicial review, *see id.* at 752, so that case has nothing to say about the significance (if any) of a preclusion provision like this one. (Defendants address other portions of *Consumers' Research* in greater detail below, *see infra* at 17-18.)

[6] For example, the Supreme Court has suggested that it would raise a "serious constitutional question" if a preclusion provision were read "to deny a judicial forum for constitutional claims." *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 681 n.12 (1986). The government has not argued here (or in any of the other cases challenging the Negotiation Program) that 42 U.S.C. § 1320f-7 forecloses judicial review of constitutional claims.

declares war, or invokes any other power that the Constitution grants it." *Patchak*, 583 U.S. at 253. And "what the Congress gives, the Congress may take away." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017).

Contrary to Plaintiffs' suggestion that congressional preclusion of judicial review over certain agency determinations is "unprecedented," Pls.' Br. at 2, such provisions are a common feature of the Medicare statute and other federal legislation. The Administrative Procedure Act (APA) itself—which creates the statutory framework for judicial review of agency action—has an explicit textual exception for the common situations in which other "statutes preclude judicial review," or when "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). Courts have applied these sorts of preclusion provisions for decades, without ever suggesting that they create (or even contribute to) a nondelegation problem.[7] Within Medicare alone, Congress has enacted dozens of similar provisions, *see, e.g.*, 42 U.S.C. §§ 1395 *et seq.* (repeatedly using the phrase "no administrative or judicial review"), which courts have applied with little controversy—including the Supreme Court and the Fifth Circuit.[8]

Similarly, contrary to Plaintiffs' repeated yet unexplained suggestion (at 2, 17-18) it is not at all "unprecedented" that the IRA "does not require notice-and-comment rulemaking," Pls.' Br. at 15—in fact, that was true of *every* federal statute until the APA was enacted in 1946. No statute required notice-and-comment procedures for any Medicare action between the creation of the program in 1965 and 1986. *See Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019). And to this day, the APA itself exempts large swaths of agency actions from this requirement,[9] to say nothing of the many other

[7] *See, e.g.*, *Webster v. Doe*, 486 U.S. 592 (1988) (no judicial review of certain agency actions under the APA); *Heckler v. Chaney*, 470 U.S. 821 (1985) (same); *S. Ry. Co. v. Seaboard Allied Milling Corp.*, 442 U.S. 444, 454 (1979) (same, under the Interstate Commerce Act); *Briscoe v. Bell*, 432 U.S. 404 (1977) (same, under the Voting Rights Act); *Schilling v. Rogers*, 363 U.S. 666 (1960) (same, under the Trading with the Enemy Act); *Arizona*, 40 F.4th at 389 (same, under the APA).

[8] *See, e.g.*, *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982); *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 532 (5th Cir. 2012); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 13 (2d Cir. 2022); *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 506 (D.C. Cir. 2019); *Knapp*, 875 F.3d at 1129.

[9] *See* 5 U.S.C. § 553(a)(1) ("military or foreign affairs"); *id.* § 553(a)(2) ("public property, loans, grants, benefits, or contracts"); *id.* § 553(b)(4)(A) ("interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice"); *id.* § 553(b)(4)(B) ("good cause").

statutes (including myriad other Medicare provisions) that more generally exempt agency actions from APA procedures.[10] If notice-and-comment were constitutionally required—or even constitutionally *relevant*—Plaintiffs would surely have identified at least one case that says so. They did not.[11]

4. Although nondelegation claims are currently on a 90-year losing streak at the Supreme Court, Plaintiffs are correct that that "twice in recent years" the Fifth Circuit has found a violation, albeit in very different circumstances than those presented here. Pls.' Br. at 13 (citing *Jarkesy v. SEC*, 34 F.4th 446, 459-63 (5th Cir. 2022), *aff'd in part on other grounds*, 603 U.S. 109 (2024); *Consumers' Rsch.*, 109 F.4th at 786, *cert. granted*, 145 S. Ct. 587 (2024). The Supreme Court granted the government's petitions for a writ of certiorari in both cases and affirmed *Jarkesy* on other grounds, while *Consumers' Research* remains pending. Regardless, both cases are readily distinguishable.

In *Jarkesy v. SEC*, 34 F.4th 446, 461 (5th Cir. 2022), the Fifth Circuit held—as one of several alternative theories about why the statutory provision in question was unconstitutional—that Congress had offered "*no guidance* whatsoever" to guide the SEC's discretion as to whether a defendant should be prosecuted in federal court or in an in-house administrative tribunal. *Id.* at 462. So the Fifth Circuit's opinion in *Jarkesy* is inapposite where, as here, Congress provided extensive guidance that satisfies the intelligible-principle test. *See supra* at 11-14. The Supreme Court ruled on other grounds. *See SEC v. Jarkesy*, 603 U.S. 109, 140-41 (2024) ("We do not reach the remaining constitutional issues and affirm the ruling of the Fifth Circuit on the Seventh Amendment ground alone.").

---

[10] *See, e.g.*, *Marcello v. Bonds*, 349 U.S. 302, 310 (1955) (discussing a statutory "exemption from the Administrative Procedure Act"); *Green Rock LLC v. IRS*, 104 F.4th 220, 226 (11th Cir. 2024) (Pryor, C.J.) ("Congress may choose to exempt an agency from notice and comment if it does so expressly.") (citation omitted); 18 U.S.C. § 3625 ("Inapplicability of the Administrative Procedure Act").

[11] Plaintiffs (at 15-16) devote more than a page of their brief to a drive-by assault on the merits of CMS's guidance implementing the IRA, even though (unlike in several other cases pending around the country) that guidance is not challenged in this case. The Court need not (and should not) opine on the legality of CMS guidance that is not at issue in this lawsuit. If the Court is nonetheless interested in understanding why Plaintiffs are mistaken about, for example, the statutory definition of a "qualifying single source drug," Pls.' Br. at 15, it may wish to consult the government's briefs in *Novo Nordisk Inc. v. HHS*, No. 24-2510 (3d Cir. Aug. 19, 2024), or *AstraZeneca Pharms. LP v. Kennedy*, No. 23-931 (D. Del. Aug. 29, 2023).

In *Consumers' Research*, the Fifth Circuit similarly concluded that a complete lack of statutory standards was cause for "grave concern[]" about a delegation's "constitutionality under the Supreme Court's nondelegation precedents." 109 F.4th at 767. But it ultimately did not issue a decision on the intelligible-principle question, holding instead that Congress's delegation to the FCC of the "core legislative power" of taxation, without meaningful standards, *id.* at 758, 766, combined with the "FCC's subdelegation" of that power "to private entities," violated the Constitution, *id.* at 756.

Here, however, there is plainly no "'Matryoshka doll' of delegations and subdelegations" to any private entity. *Id.* at 784. Nor did Congress delegate the power to tax (or anything analogous), which "has always been an exclusively legislative function." *Id.* at 767. To the contrary: negotiating contracts, free from "dilatory restraints," is a routine and traditional *Executive Branch* function. *See Perkins*, 310 U.S. at 127 (recognizing "the traditional principle of [Congress] leaving purchases necessary to the operation of our Government to administration by the executive branch of Government"). Accordingly, even if the Supreme Court were to endorse the Fifth Circuit's reasoning in full, it would still be no help to Plaintiffs here. Nevertheless, in the interest of judicial economy, and given Plaintiffs' heavy reliance on *Consumers' Research*—they cite it 17 times—the Court may wish to await a decision in that case (expected by June 2025) before deciding this one.

II. Plaintiffs' excise-tax claim is both beyond the subject-matter jurisdiction of this Court and meritless.

Plaintiffs' Eighth Amendment excise-tax claim should be dismissed because it runs afoul of two independent jurisdictional barriers.[12] The claim would also fail on the merits.

A. Plaintiffs' excise-tax claim is not redressable in this suit.

Plaintiffs lack Article III standing to press their constitutional challenge to the excise tax. To show Article III standing, a plaintiff "bears the burden of establishing" that it has "suffered an injury

[12] The Court may dismiss the claim on either of those grounds. *See Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007). Dismissal on the basis of the AIA would be more efficient, however, because Plaintiffs cannot overcome the AIA by filing a new or revised complaint against the proper defendants. *Cf. Boehringer Ingelheim*, 2024 WL 3292657, at *21 (dismissing on AIA grounds and declining to reach redressability).

in fact . . . that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998). Redressability must be established "for each claim that [plaintiffs] press and for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021); *see also id.* ("[S]tanding is not dispensed in gross.").

Plaintiffs' excise-tax claim cannot be redressed in this suit against HHS and CMS. *See Haaland v. Brackeen*, 599 U.S. 255, 292 (2023). Plaintiffs seek two remedies with respect to the section 5000D tax: injunctive and declaratory relief. *See* Compl., Prayer for Relief ¶¶ 2, 5. Even if such relief were available, *but see infra* at 20-31, neither remedy would provide Plaintiffs with any redress, and Plaintiffs therefore lack standing.

Take the requested injunctive relief first. Plaintiffs ask the Court to "[e]njoin HHS from enforcing the IRA excise tax." Compl., Prayer for Relief ¶ 5. But HHS does not administer the IRA's tax provisions, which are codified in the Internal Revenue Code. *See* 26 U.S.C. § 5000D. Rather, the Department of the Treasury, of which the IRS is a part, is charged with enforcing section 5000D and interpreting its provisions. *Compare id.* § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance . . . ."), *with id.* § 5000D(b)(1)(B) (referring to "the Secretary of Health and Human Services"), *and id.* § 5000D(c)(1)(A)(i) (same); *see also* 26 U.S.C. § 7701(a)(11)(B) ("When used in this title, . . . [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."); *id.* §§ 7801(a)(1), 7803(a)(2). And, indeed, the IRS has begun to do just that. *See* IRS Notice § 3.01 (scope of taxable sales), *id.* § 3.02 (applicable tax percentage); *see also Excise Tax on Designated Drugs; Procedural Requirements*, 89 Fed. Reg. 55507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47); *Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025). But the Court cannot enter judgment against Treasury and the IRS because they are "not parties to the suit" and they would not be "obliged to honor an incidental legal determination the suit produced." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 569 (1992) (plurality op.); *see also Brackeen*, 599 U.S. at 292 (no redressability where order would not enjoin entities carrying out challenged provisions).

Plaintiffs' request for a declaratory judgment—asking the Court to "[d]eclare that the IRA excise tax violates the Eighth Amendment Excessive Fines Clause," Compl., Prayer for Relief ¶ 2—"suffers from the same flaw." *Brackeen*, 599 U.S. at 293. "[J]ust like suits for every other type of remedy, declaratory-judgment actions must satisfy Article III's case-or-controversy requirement." *California v. Texas*, 593 U.S. 659, 672 (2021). "The [DJA] does not exempt federal district courts from the constitutional requirement that there be an actual controversy *between the parties*." *Standard Fire Ins. v. Sassin*, 894 F. Supp. 1023, 1026 (N.D. Tex. 1995) (emphasis added). "But again, [Treasury and IRS] are nonparties who would not be bound by the judgment." *Brackeen*, 599 U.S. at 293. Thus, Plaintiffs' excise-tax challenge "would not be settled between [Plaintiffs] and the officials who matter—which would leave the declaratory judgment powerless to remedy the alleged harm." *Id.* And "[w]ithout preclusive effect, a declaratory judgment is little more than an advisory opinion." *Id.*

B. Plaintiffs' excise-tax claim is barred by the Anti-Injunction Act and the tax exception to the Declaratory Judgment Act.

Plaintiffs' excise-tax claim is independently barred by the AIA and the tax exception to the DJA. "Under the Anti-Injunction Act, Congress has provided that, absent limited exceptions, 'no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person.'" *Franklin v. United States*, 49 F.4th 429, 434 (5th Cir. 2022) (quoting 26 U.S.C. § 7421(a)). "When the AIA applies, it divests courts of subject-matter jurisdiction." *Matter of Westmoreland Coal Co.*, 968 F.3d 526, 533 (5th Cir. 2020). The tax exception to the DJA similarly bars courts from issuing declaratory judgments "with respect to Federal taxes." 28 U.S.C. § 2201(a).

1. "The [AIA] apparently has no recorded legislative history, but its language could scarcely be more explicit—'no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court . . . .'" *Bob Jones Univ. v. Simon*, 416 U.S. 725, 736 (1974). "Because of the [AIA], taxes can ordinarily be challenged only after they are paid, by suing for a refund." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 543 (2012) (*NFIB*). "Courts have zealously guarded this rule" "that a taxpayer must 'pay first and litigate later.'" *Franklin*, 49 F.4th at 434.

The AIA applies with equal force to constitutional challenges. *Alexander v. Ams. United Inc.*, 416 U.S. 752, 759 (1974). "Merely couching" a challenge to a tax "in constitutional terms will not allow a court to entertain the claim in contravention of the AIA." *Franklin v. United States*, No. 3:20-cv-1303, 2021 WL 4458377, at *7 (N.D. Tex. Sept. 29, 2021), *aff'd*, 49 F.4th 429 (5th Cir. 2022).

To determine whether the AIA applies, courts ask (1) whether the exaction at issue is a "tax," and (2) whether the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a). Because both are true here, the excise-tax claim is barred by the AIA.

First, the section 5000D excise tax is a "tax" for AIA purposes because Congress "label[ed]" it as such. *See NFIB*, 567 U.S. at 564. The AIA and the IRA's excise tax are "creatures of Congress's own creation" and, therefore, "[h]ow they relate to each other is up to Congress, and the best evidence of Congress's intent is the statutory text." *Id.* at 544. Accordingly, "even where [a] label was inaccurate" for constitutional purposes, the Supreme Court has "applied the [AIA]" to bar preemptive challenges "to statutorily described 'taxes.'" *Id.* (citation omitted). "With the AIA, form—specifically, the label Congress uses—does matter over substance." *Westmoreland Coal Co.*, 968 F.3d at 534.

Congress labeled the excise tax a "tax"—a point that Plaintiffs do not dispute. Section 5000D refers to a "tax" nearly a half dozen times. *See* 26 U.S.C. § 5000D(a) ("a tax"); *id.* § 5000D(a)(1) ("such tax"); *id.* § 5000D(a)(2) (same); *id.* § 5000D(c) ("Suspension of tax"); *id.* § 5000D(f)(2) ("the tax imposed by this section"). Further, Congress codified section 5000D in Title 26—*i.e.*, the Internal Revenue Code—separate from the rest of the IRA's drug-negotiation provisions. *See* Pub. L. No. 117-169, § 11003 ("Subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following . . . ."). For AIA purposes, the statutory text is clear: section 5000D imposes a "tax."

Plaintiffs' only response is that the excise tax is not subject to the AIA because it "does not even seek to collect revenue," citing estimates from the Congressional Budget Office (CBO) and the Joint Commission on Taxation. *See* Pls.' Br. at 9, 22. But even setting aside the soundness of those predictions, the AIA simply "draws no distinction between regulatory and revenue-raising tax rules." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 225 (2021). "That is, a so-called regulatory tax—'a tax designed mainly to influence private conduct, rather than to raise revenue'—does not have a special pass from

the AIA." *Novartis*, 2024 WL 4524357, at *3 (quoting *CIC Servs.*, 593 U.S. at 224). Therefore, because Congress labeled the § 5000D tax a "tax," it is a "tax" for AIA purposes.

Second, the purpose of Plaintiffs' excise-tax claim is to "restrain[] the assessment or collection" of the section 5000D tax. 26 U.S.C. § 7421(a). In considering a claim's purpose, courts look to "the claims brought and injuries alleged" as well as "the relief the suit requests." *CIC Servs.*, 593 U.S. at 217-18. The excise-tax claim squarely targets the tax. *See, e.g.*, Compl. ¶¶ 93-104, 135-41. And the relief requested here to "[e]njoin HHS from enforcing the IRA excise tax" asks the Court to restrain the assessment or collection of that tax. Compl., Prayer for Relief ¶ 5. "These allegations leave little doubt that a primary purpose of" the tax claim "is to prevent the [IRS] from assessing and collecting" the excise tax. *Bob Jones*, 416 U.S. at 738.

2. In the "face of the AIA's express prohibition," Plaintiffs try to fit their claim into one of two narrow exceptions to the AIA. *See Novartis*, 2024 WL 4524357, at *4. Plaintiffs' effort—like that of every individual manufacturer to challenge the excise tax—comes up short. *See id.* (holding that no exception applies); *Boehringer Ingelheim*, 2024 WL 3292657, at *21 (same). Neither of the two judicially created exceptions—the *Williams Packing* and the *South Carolina* exceptions—applies here. *See South Carolina v. Regan*, 465 U.S. 367 (1984); *Enochs v. Williams Packing & Navig. Co.*, 370 U.S. 1 (1962).

A taxpayer's "burden under *Williams Packing* is very substantial." *Flynn v. United States*, 786 F.2d 586, 591 (3d Cir. 1986). This "stringent" exception requires "proof of the presence of two factors" to avoid "the literal terms of" the AIA: "first, irreparable injury, the essential prerequisite for injunctive relief in any case; and second, certainty of success on the merits." *Bob Jones*, 416 U.S. at 737 (discussing *Williams Packing*, 370 U.S. at 6-7). "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Ams. United*, 416 U.S. at 758. Plaintiffs "cannot meet either of these requirements." *Boehringer Ingelheim*, 2024 WL 3292657, at *22; *see also Novartis*, 2024 WL 4524357, at *4 (same).

First, because a refund suit is an adequate remedy, Plaintiffs cannot establish that they or their members will suffer irreparable harm absent preemptive injunctive relief. "This is not a case in which an aggrieved [taxpayer] has no access at all to judicial review." *Bob Jones*, 416 U.S. at 746. A

manufacturer that wishes to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims, *see* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491—as two other district courts have correctly held, *see Boehringer Ingelheim*, 2024 WL 3292657, at *22; *see also Novartis*, 2024 WL 4524357, at *4 (same). That is particularly true given that the excise tax is imposed on each "sale" of a designated drug, 26 U.S.C. § 5000D(a), and is thus a "divisible tax," meaning "one that represents the aggregate of taxes due on multiple transactions (*e.g.*, sales of items subject to excise taxes)," *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). A taxpayer challenging a divisible tax need only pay "the excise tax on a single transaction [to] satisfy" the general rule that it must fully pay the tax before seeking a refund. *Id.*; *see also Flora v. United States*, 362 U.S. 145, 171-75 nn.37, 38 (1960). And, while a refund suit is pending, the IRS typically does not collect the balance of any divisible tax that would otherwise be due, except when unusual circumstances warrant. IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6) ("When a refund suit is pending on a divisible assessment, the Service will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy.").

Plaintiffs nonetheless protest that a manufacturer may continue to accrue tax liability during the pendency of the refund suit. *See* Pls.' Br. at 23. As another district court explained, that possibility is insufficient to avoid the AIA because the relevant harm is that which is suffered "between the request for an injunction and final disposition of the case on the merits." *Boehringer Ingelheim*, 2024 WL 3292657, at *22 (citation omitted). And in fact, that harm "is minimal": a manufacturer would "need to pay the excise tax on only one transaction in order to bring the refund suit." *Id.* "If [the manufacturer] ultimately prevailed, the IRS could not require it to pay the tax at all and would have to refund any amount [the manufacturer] had already paid. If it did not prevail, the IRS could constitutionally require it to pay the tax, which would mean the tax inflicted no actionable harm." *Id.*

Second, in any event, even a showing of irreparable harm would be insufficient to set aside the AIA. *See Williams Packing*, 370 U.S. at 6. Plaintiffs would also have to show that, "under the most liberal view of the law and the facts," "it is clear that under no circumstances could the Government ultimately prevail" on its defense of the merits. *Id.* at 7; *see also McCabe v. Alexander*, 526 F.2d 963, 965

(5th Cir. 1976) ("[T]he court must view the facts in the light most favorable to the Government."). For the reasons set forth below, *see infra* at 24-31, Plaintiffs "cannot meet this demanding standard because [their] Eighth Amendment claim is novel and, so, far from certain," *Boehringer Ingelheim*, 2024 WL 3292657, at *23. Like the pharmaceutical manufacturers in every other case to challenge the excise tax, Plaintiffs have "identified no case in which a court has applied the Excessive Fines Clause to a monetary amount that was not connected to criminal conduct or a criminal proceeding." *Id.*; *see also Novartis*, 2024 WL 4524357, at *5 ("Plaintiff has not identified a case that has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes.").

The *South Carolina* exception similarly offers no safe harbor. That exception is a "very narrow" one that applies only when Congress has not "provided an alternative avenue for an aggrieved party to litigate its claims," necessitating the party harmed by the tax to find a third party to assert the legal issues. *South Carolina*, 465 U.S. at 381. This case is a far cry from "the unique factual pattern" in *South Carolina*, where a sovereign State could not bring a refund suit itself and had to rely on third-party bondholders to challenge a change in the tax code that stripped certain state-issued bonds of their tax-exempt status. *RYO Mach., LLC v. U.S. Dep't of Treasury*, 696 F.3d 467, 472 (6th Cir. 2012) (quoting *Am. Soc. of Ass'n Execs. v. Bentsen*, 848 F. Supp. 245, 250 (D.D.C. 1994)).

3. Declaratory relief is similarly prohibited by the tax exception to the DJA, which bars courts from issuing declaratory judgments "with respect to Federal taxes." 28 U.S.C. § 2201(a). The "federal tax exception to the [DJA] is at least as broad as the [AIA]." *Bob Jones*, 416 U.S. at 732 n.7; *see also McCabe v. Alexander*, 526 F.2d 963, 965 (5th Cir. 1976) ("Having found the [AIA] applicable, we necessarily conclude that no declaratory relief is available.").[13]

C. Plaintiffs' excise-tax claim is meritless.

Even if the Court were to reach the merits of the tax claim, that claim would fail because the tax does not violate the Excessive Fines Clause. The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."

[13] Both the AIA and the tax exception to the DJA are jurisdictional bars. *See Rivero v. Fid. Invs., Inc.*, 1 F.4th 340, 344 (5th Cir. 2021) ("the DJA's federal-tax exception" is "jurisdictional").

U.S. Const. amend. VIII. "Taken together, these Clauses place 'parallel limitations' on 'the power of those entrusted with the criminal-law function of government.'" *Timbs v. Indiana*, 586 U.S. 146, 151 (2019) (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 263 (1989)). "The purpose of the Eighth Amendment"—both the Excessive Fines Clause and the Cruel and Unusual Punishments Clause—"was to limit the government's power to punish." *Austin v. United States*, 509 U.S. 602, 609 (1993). The threshold question in any Excessive Fines Clause case then is whether the challenged exaction constitutes "punishment for an offense"—*i.e.*, whether it is a "fine" covered by the Eighth Amendment. *United States v. Bajakajian*, 524 U.S. 321, 328 (1998). Only if the exaction is deemed punishment does a court consider whether the fine is unconstitutionally excessive. The excise tax does not violate the Excessive Fines Clause because it is neither a "fine" nor "excessive."

1. The excise tax is not a "fine" covered by the Eighth Amendment because it is not "punishment for some offense." *Bajakajian*, 524 U.S. at 327. "[A]t the time the Constitution was adopted, the word 'fine' was understood to mean a payment to a sovereign as punishment for some offense." *Id.* (cleaned up). "Then, as now," fines were typically imposed as punishments in criminal prosecutions. *Browning-Ferris Indus.*, 492 U.S. at 265. The Court has never characterized an exaction with no connection to either criminal activity or a criminal proceeding as "punishment for some offense," let alone punishment that violates the Excessive Fines Clause. *See Boehringer Ingelheim*, 2024 WL 3292657, at *23; *Novartis*, 2024 WL 4524357, at *5.

The only instances in which the Supreme Court has found certain penalties and forfeitures to be "punishment" within the scope of the Excessive Fines Clause involved a post-conviction sanction, *see Bajakajian*, 524 U.S. at 325 (person convicted of willfully violating reporting requirement shall forfeit property "involved in such offense"), or forfeiture assessed against property used in the commission of a crime for which the owner had been convicted, *see Austin*, 509 U.S. at 622 (property used to facilitate drug crimes subject to civil forfeiture). None of the features of the civil forfeiture in *Austin* or the criminal forfeiture in *Bajakajian* is present here. *See United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022) ("[U]nlike [the] forfeitures held to constitute 'punishment' in both *Austin* and *Bajakajian*, this civil penalty"—"imposed following an administrative tax audit"—"is not tied to any criminal

sanction."), *cert. denied*, 143 S. Ct. 552 (2023). Unlike civil or criminal forfeiture, "taxes historically have not been viewed as punishment." *United States v. Beaty*, 147 F.3d 522, 525 (6th Cir. 1998). The other three *Austin* factors are similarly absent. First, section 5000D does not contain an innocent-taxpayer exception and imposition of the tax does not depend on any particular level of culpability. *See generally* 26 U.S.C. § 5000D. Second, the excise tax is not tied to the commission of any crime; rather, tax liability is triggered by the lawful choices of the taxpayer in connection with the Negotiation Program. *See id.* § 5000D(a), (b), (e)(1). Third, Congress did not indicate that the tax is meant to supplement "traditional criminal sanctions of fine and imprisonment" to adequately "deter or punish" illegal activity. *See Austin*, 509 U.S. at 620. And, unlike the criminal forfeiture in *Bajakajian*, the tax is not "imposed at the culmination of a criminal proceeding," does not "require[] [a] conviction of an underlying felony," and does not distinguish in its rate or scope between different levels of culpability. *See Bajakajian*, 524 U.S. at 328.

2. Having identified no case in which an exaction untethered from criminal conduct or criminal proceedings was deemed "punishment for some offense" under the Excessive Fines Clause, Plaintiffs turn to two Double Jeopardy Clause cases. *See* Pls.' Br. at 19 (citing *Dep't of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767 (1994); *Dye v. Frank*, 355 F.3d 1102 (7th Cir. 2004)). Those are the *only* cases Plaintiffs identify in which a tax was held to be punishment; they do not cite *any* case in which a tax was deemed to be "punishment for some offense" (*i.e.*, a "fine") under the Excessive Fines Clause. And both cases that Plaintiffs cite—involving drug taxes related to criminal offenses—reinforce why the tax here is *not* punishment.

As a preliminary matter, the analytical framework used by the Supreme Court in *Kurth Ranch* undermines a core premise of Plaintiffs' argument: that the excise tax is a "fine" if it "serves in part to punish." Pls.' Br. at 19 (quoting two-justice concurrence in *Tyler v. Hennepin Cnty., Minnesota*, 598 U.S. 631, 648 (2023) (Gorsuch, J., concurring)). The Court first adopted that test in *United States v. Halper*, 490 U.S. 435 (1989), a case involving a $130,000 civil penalty on the heels of a 65-count criminal conviction that also resulted in a two-year prison sentence and a $5,000 fine. 490 U.S. at 437-38. Because the post-conviction civil fine could not "fairly be said solely to serve a remedial purpose, but

rather can only be explained as also serving either retributive or deterrent purposes," the Court held it was "punishment" for Double Jeopardy purposes. *Id.* at 448.[14]

The Supreme Court has never applied this deterrent-in-part test in the tax context, and, in *Kurth Ranch*, the Court rejected its application to a state drug tax. 511 U.S. at 776. The Court concluded that the *Halper* test was inapplicable to a Double Jeopardy Clause challenge to a Montana tax on illegal drug possession because, while *Halper* held that certain civil *penalties* could constitute punishment, "*Halper* did not . . . consider whether a *tax* may similarly be characterized as punitive." 511 U.S. at 767, 778 (emphasis added). Because "tax statutes serve a purpose quite different from civil penalties," "*Halper*'s method of determining whether the exaction was remedial or punitive 'simply does not work in the case of a tax statute.' Subjecting Montana's drug tax to *Halper*'s test for civil penalties is therefore inappropriate." *Id.* at 784 (citation omitted). Accordingly, "neither a high rate of taxation nor an obvious deterrent purpose automatically marks [a] tax as a form of punishment." *Id.* at 780; *contra* Pls.' Br. at 19-20. "Whereas fines, penalties, and forfeitures are readily characterized as sanctions," absent "[o]ther unusual features," "an exaction labeled as a tax" is not deemed punishment, even if it is accompanied by a "deterrent purpose." 511 U.S. at 779-81; *id.* at 780-81 ("[M]any taxes that are presumed valid, such as taxes on cigarettes and alcohol, are also both high and motivated to some extent by an interest in deterrence . . . ."); *see also United States v. Ross*, 458 F.2d 1144, 1145 (5th Cir. 1972) ("every tax is regulatory to some extent . . . that an act accomplishes another purpose than raising revenue does not invalidate it"); *contra* Pls.' Br. at 19-20.

The facts of *Kurth Ranch* are equally unhelpful to Plaintiffs. The marijuana tax there was deemed "punishment" only because of a host of "unusual features" and "anomalies" absent here. *See* 511 U.S. at 781-83 ("so-called tax"[15] (1) was "conditioned on the commission of a crime," (2) applied

[14] The Court later abrogated *Halper* in *Hudson v. United States*, 522 U.S. 93, 102 (1997) (noting that "all civil penalties have some deterrent effect" and rejecting "*Halper*'s test for determining whether a particular sanction is 'punitive'" under the Double Jeopardy Clause).

[15] Plaintiffs similarly refer to the section 5000D tax as a "so-called 'excise tax.'" Pls.' Br. at 8. That characterization, as the Court's description of the Montana drug tax shows, does not alter the punishment analysis. What mattered in *Kurth Ranch* was that the Montana tax was "labeled as a tax."

only to those already arrested for marijuana possession, and (3) was "levied . . . on previously confiscated goods" that the "taxpayer neither own[ed] nor possess[ed] when the tax [was] imposed").

None of the "unusual features" and "concoction of anomalies" that made the Montana tax "exceptional" is present here: the excise tax is not conditioned on the commission of a crime, it is not exacted after an arrest, and it is not levied on previously confiscated goods. *See id.* at 781-83. Indeed, the tax does not follow any determination that the taxpayer has engaged in any unlawful activity. *See generally* 26 U.S.C. § 5000D. Further, unlike the tax assessment in *Kurth Ranch*, which required the taxpayer to pay a *multiple* of gross revenue (approximately four times), 511 U.S. at 780 n.17, a manufacturer's excise-tax obligations may be satisfied by paying a *fraction* of gross revenue because the tax, when not separately invoiced, ranges from 65% to 95% of the amount charged for a designated drug, IRS Notice § 3.02; *see also* 26 U.S.C. § 5000D(d).[16]

Further, unlike the tax in *Kurth Ranch*, the excise tax serves a remedial purpose in compensating the public fisc for losses incurred from a manufacturer failing to agree to a maximum fair price and continuing to sell its drugs to Medicare beneficiaries, potentially at much higher prices. *Contra* Pls.' Br. at 19 (asserting "sole purpose" of excise tax to punish). Indeed, courts regularly recognize that

---

511 U.S. at 780. Given that label, the Court refused, unlike in *Halper* and *Austin*, to hold that the tax constituted punishment on the sole basis that the tax partly had a deterrent purpose.

[16] Plaintiffs maintain that the tax "reaches 1,900%" of a "drug's total U.S. revenues." Pls.' Br. at 19. But the IRS has made clear, in a notice that "taxpayers may rely on" now, IRS Notice § 4, that—assuming a manufacturer does not separately invoice the tax and assuming 271 days have passed—a covered taxpayer would owe a $95 tax out of $100 charged for a drug by a manufacturer—that is 95%, not 1900%. *See* IRS Notice § 3.02. Further, that notice explains that the tax applies only to sales "*under the terms of Medicare*"—*i.e.*, only those drugs dispensed, furnished, or administered to Medicare beneficiaries. *Id.* § 3.01 (emphasis added). Plaintiffs appear to dispute IRS's interpretation of section 5000D, *see* Pls.' Br. at 9 n.2, but Plaintiffs do not bring a standalone claim as to the notice or the subsequent Notice of Proposed Rulemaking. That is unsurprising, given that the latter is not final agency action subject to review and, in any event, the IRS's interpretation—at least in comparison to the one advanced by Plaintiffs—operates to Plaintiffs' benefit, and Plaintiffs would therefore lack standing to challenge it. In any event, because Plaintiffs bring a facial challenge—before any tax has been assessed or collected, in violation of the AIA—it must establish that the tax is unconstitutional in all applications. *City of Los Angeles v. Patel*, 576 U.S. 409, 418 (2015). Therefore, to the extent the parties have a dispute about the applicable rate of tax that would apply, Plaintiffs are entitled to relief only if the excise tax as interpreted and applied by the IRS is unconstitutional.

even tax *penalties* have a remedial purpose. *See Helvering v. Mitchell*, 303 U.S. 391, 401 (1938) (describing "[t]he remedial character of sanctions imposing additions to a tax"); *Dewees v. United States*, 272 F. Supp. 3d 96, 100-01 (D.D.C. 2017) ("courts have erected 'an insurmountable wall of tax cases'" establishing that "tax penalties are remedial"), *aff'd*, 767 F. App'x 4 (D.C. Cir. 2019).[17]

The Seventh Circuit's decision in *Dye* is similarly inapposite. Applying a seven-factor test, the court held that the Wisconsin drug tax was the "rare tax statute" that "is so punitive in either purpose or effect that it is subject to double jeopardy analysis at all." 355 F.3d at 1108. The court's holding rested on key facts missing here: "the tax is only applied to behavior that is already a crime," was "created in order to deter criminal conduct," and the amount of the tax was "approximately five times the market value of the drugs" ($400 tax assessment and penalty on a gram of cocaine that could be sold for "approximately $80"). *Id.* at 1104-05.[18]

3. The test used to determine whether a "fine" is "excessive" under the Excessive Fines Clause only reinforces the conclusion that the excise tax is not "punishment." A fine is not excessive if the "amount of the [fine] bear[s] *some* relationship to the gravity of the offense that it is designed to punish," an inquiry that requires a court to "compare the amount of the [fine] to the gravity of the defendant's offense." *Bajakajian*, 524 U.S. at 334, 336-37 (emphasis added). That question has no bearing here given the lack of any "offense" or any "design[] to punish." *Id.* at 334.

[17] Citing a CBO report, Plaintiffs assert that the government does not anticipate raising any revenue from the excise tax. Pls.' Br. 9. To the extent that Plaintiffs are contending that a CBO prediction can determine whether a tax has a remedial purpose, Plaintiffs are wrong. "[A] CBO cost estimate is not persuasive evidence of congressional intent." *Laumann v. NHL*, 56 F. Supp. 3d 280, 296 (S.D.N.Y. 2014); *see also Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009) ("the CBO is not Congress, and its reading of the statute is not tantamount to congressional intent"). Regardless, Plaintiffs' argument confuses purposes and effects. The excise tax can and does have a remedial purpose even if, by Plaintiffs' telling, a manufacturer would not engage in the conduct that would cause the harm the excise tax is designed to remedy. *Cf. United States v. Sanchez*, 340 U.S. 42, 44 (1950) (tax is valid "even [if it] definitely deters the activity taxed").

[18] Plaintiffs cite the Fifth Circuit's earlier decision describing the tax as "part of the IRA's 'penalty phase.'" Pls.' Br. at 18 (quoting *NICA*, 116 F.4th at 495). As Plaintiffs know, the jurisdictional and merits issues addressed here had not yet been briefed. The Fifth Circuit did not hold that the tax constituted a "fine," let alone one in violation of the Eighth Amendment.

Plaintiffs nonetheless argue that the excise tax is "grossly disproportionate" because the excise tax punishes conduct that "is not even considered wrongful, must less unlawful." Pls.' Br. at 21. That is precisely the point: because the tax is not triggered by the commission of *any* offense—reprehensible or otherwise—it is not "punishment for some offense" and therefore is not a "fine" under the Excessive Fines Clause. Embracing Plaintiffs' argument would lead to absurd results: *most* taxes would be unconstitutionally disproportionate because they are assessed following innocuous conduct like working or shopping. That would stretch the Eighth Amendment, which merely "limit[s] the government's power to punish," beyond recognition. *Austin*, 509 U.S. at 609.

4. If the Court were to reach the excessiveness inquiry, the excise tax would not be a "grossly disproportionate" fine. Pls.' Br. at 21. First, "strict proportionality" is not required; a fine is constitutional unless it is grossly disproportional to the offense. *Bajakajian*, 524 U.S. at 336 (adopting "standard of gross disproportionality articulated in" "Cruel and Unusual Punishments Clause precedents"). Second, that inquiry requires "substantial deference" to Congress. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *Bajakajian*, 524 U.S. at 336 ("judgments about the appropriate punishment for an offense belong in the first instance to the legislature"). Because "Congress is a representative body, its pronouncements regarding the appropriate range of fines for a crime represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Dr.*, 175 F.3d 1304, 1309 (11th Cir. 1999). "No matter how excessive (in lay terms) an administrative fine may appear, if the fine does not exceed the limits prescribed by the statute authorizing it, the fine does not violate the Eighth Amendment." *Newell Recycling Co. v. EPA*, 231 F.3d 204, 210 (5th Cir. 2000).

Plaintiffs fail to overcome the "strong presumption" of constitutionality here, as the *Bajakajian* factors make clear. First, unlike in *Bajakajian*, where the defendant who failed to report the cash in his possession did "not fit into the class of persons for whom the statute was principally designed" because he was not a "money launderer, a drug trafficker, or a tax evader," 524 U.S. at 338, any "manufacturer" "of any designated drug" against whom the excise tax is assessed is an entity for which that statute was designed, 26 U.S.C. § 5000D(a)—a point Plaintiffs do not contest. Second, while the "[f]ailure to report" currency "caused no loss to the public fisc" in *Bajakajian*, 524 U.S. at 339

(government "deprived only of . . . information"), here the fisc will likely incur significant losses, and seniors will likely face substantially higher costs, if a manufacturer that chooses to continue participating in Medicare declines to agree to a maximum fair price and sells that drug to Medicare at a higher price than the statutory ceiling. Third, unlike in *Bajakajian*, where there was "no inherent proportionality" in requiring forfeiture of the full amount of undisclosed cash, *see id.*, the excise tax is proportional to the harm to the fisc: where a manufacturer of a designated drug has refused to fully participate in the Negotiation Program, the more it sells its drug to Medicare (presumably at a price higher than that which the manufacturer could have agreed to as a "maximum fair price"), the greater the loss to the public and the higher the tax liability, *see* 26 U.S.C. § 5000D(b)(2); IRS Notice § 3. Indeed, because the tax attaches only to sales of the drug that are reimbursed by Medicare, the tax necessarily recoups only a portion of the outlays that the Medicare program or Medicare beneficiaries have paid for the drug. And, where the tax is not separately invoiced, the ratio of the tax to the amount charged by the manufacturer—between 65% and 95%—is within the range of constitutionally permissible exactions. *See, e.g.*, *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996) (81% civil fraud penalty).[19]

Accordingly, even if Plaintiffs had sued the proper defendants and even if the AIA and DJA did not preclude jurisdiction, Plaintiffs' Eighth Amendment claim would fail on the merits because the excise tax is neither a fine nor a grossly disproportionate one.

---

[19] Selected drugs, by definition, have been on the market without competition for a minimum of seven years. 42 U.S.C. § 1320f-1(e). Outside experts project that each of the manufacturers of the selected drugs have recouped their fixed-cost investments in those drugs during this time period, long in advance of the drug's selection for negotiation. *See* Richard G. Frank & Caitlin Rowley, *Medicare Negotiations Won't Keep Big Pharma from Making a Fortune*, Bloomberg Law (Sept. 5, 2023), https://www.bloomberg.com/opinion/articles/2023-09-05/medicare-negotiations-won-t-keep-big-pharma-from-making-a-fortune; *see also* Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, 2019 JAMA Network Open 186875 (2019). And, once a manufacturer has recouped its fixed costs, its marginal cost of producing small-molecule drugs is generally "just pennies per pill." CBO, *Prescription Drugs: Spending, Uses, and Prices* 20 (2022), https://perma.cc/27R2-3SN4. Some manufacturers accordingly may find it to be in their business interest to continue to make Medicare-reimbursable sales of their selected drugs and to pay a portion of that Medicare reimbursement back in the form of the excise tax. *Contra* Pls.' Br. at 9 ("no manufacturer could afford to pay" excise tax).

III. Plaintiffs' due process claims are meritless.

The IRA provisions establishing the Negotiation Program do not violate Plaintiffs' due process rights. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. The threshold "inquiry in every due process challenge is therefore whether the plaintiff has been deprived of a protected interest" in liberty or property. *Am. Mfrs. Mut. Ins.*, 526 U.S. at 59. Plaintiffs allege that the Negotiation Program deprives manufacturers, providers, and patients of due process, but—as every other court to have addressed a due process challenge to the Negotiation Program has held—none of Plaintiffs' theories establish a deprivation of any constitutionally protected interest. "Without a cognizable interest in liberty or property, 'there is nothing subject to Due Process protections and our inquiry ends.'" *James v. Cleveland Sch. Dist.*, 45 F.4th 860, 864 (5th Cir. 2022) (quoting *Hampton Co. Nat'l Sur., LLC v. Tunica Cnty.*, 543 F.3d 221, 225 (5th Cir. 2008)). There is thus no need for the Court to address "the three-factor test articulated in *Mathews v. Eldridge*, 424 U.S. 319 (1976)." Pls.' Br. 24.[20]

A. Plaintiff PhRMA's due process claim lacks merit.

Plaintiffs assert that the Negotiation Program deprives manufacturers (such as those represented by PhRMA) of protected interests (1) in patents and (2) of the "right to offer access to their products at prices set by voluntary agreements." Pls.' Br. at 25-26. As multiple courts have already held, neither theory supports a due process violation here.

1. Patents are a form of property. But Plaintiffs fail to explain how the Negotiation Program deprives anyone of any patent rights. Plaintiffs urge that the Negotiation Program threatens the "full

[20] Plaintiffs halfheartedly suggest that the Fifth Circuit has already resolved the due process claims in their favor. *See, e.g.*, Pls.' Br. at 24 (asserting that "the Fifth Circuit necessarily determined that Plaintiffs have a property interest that triggers the protections of the Due Process Clause"). In fact, the Fifth Circuit decided only the question of whether Plaintiff NICA had sufficiently alleged facts to invoke federal jurisdiction. *See NICA*, 116 F.4th at 509. That approach was unsurprising, because this Court dismissed Plaintiffs' claims on grounds of jurisdiction and venue, without reaching the merits at all. *See id.* at 494. For that reason, no party briefed the merits of *any* of Plaintiffs' claims at the Fifth Circuit. In fact, before today's filing, Defendants have never filed any brief addressing the merits of this case—not in the Fifth Circuit, and not in this Court. There is no basis to read to the Fifth Circuit's opinion as having prejudged the merits of this case, in an opinion about jurisdiction, before the government ever filed any brief.

exercise of the exclusionary power" that a patentee enjoys. *Id.* at 26 (quoting *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007)). But "the federal patent laws do not create any affirmative right to . . . sell anything," *Biotechnology Indus. Org.*, 496 F.3d at 1372 (quoting *Leatherman Tool Grp. Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)), much less to command a particular price. While a patentee may use its exclusive right to sell a drug as leverage in the marketplace, the freedom from competitive pressure conferred by the period of exclusivity does not entitle the patentee to any particular revenue from any particular buyer.

The same holds true when the buyer is the government. "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam); *see Perkins*, 310 U.S. at 127 (emphasizing the government's authority to "determine those with whom it will deal"). "Just like private individuals and businesses, 'the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.'" *AstraZeneca*, 719 F. Supp. 3d at 395 (emphasis omitted) (quoting *Perkins*, 310 U.S. at 127). There is no overriding right inherent in a patent that entitles the holder to compel anyone, including the government, to pay more for a good than they are willing to pay.

Indeed, pursuant to the government's power to determine the prices it will pay for goods and services, other federal agencies have for decades negotiated with drug manufacturers over the price paid for patented drugs in other government programs. *See* 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, drug manufacturers have long entered into agreements to provide patented drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act). And the government regularly negotiates the price it will pay for other goods. *See, e.g.*, 48 C.F.R. pts. 15, 215. Just as military contractors have no right to sell their patented products to the Department of Defense at prices above what the government is willing to pay, pharmaceutical companies have no right to sell drugs to Medicare at any particular price.

Plaintiffs' acknowledgement that "the dictates of the marketplace" can affect its revenues without threatening any patent rights, Pls.' Br. at 26 (quoting *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)), is fatal to their claim. In negotiating the price that Medicare will pay for drugs, the government is acting as a market participant. *Cf.* Ex. 1, Buchmueller Decl. ¶¶ 20-25 (analyzing negotiating leverage of both CMS and manufacturers). The Negotiation Program sets the terms of the government's offer to pay for certain drugs, and manufacturers have no right to force the government to pay for its drugs on different terms. Plaintiffs' contrary view is inconsistent both with how the marketplace works and with Congress's clear authority to control federal spending. The Negotiation Program reflects Congress's judgment that the federal government has been spending far too much on high-cost prescription drugs, and the government has a strong interest in controlling federal spending to promote the general welfare. *See Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place . . . ."). Because Plaintiffs "ha[ve] no legitimate claim of entitlement to sell its drugs to the Government at any price other than what the Government is willing to pay, [their] due process claim fails as a matter of law." *AstraZeneca*, 719 F. Supp. 3d at 396.

2. Plaintiffs are also incorrect that the Negotiation Program deprives manufacturers of an alleged "right to offer access to their products at prices set by voluntary agreements." Pls.' Br. at 26. The Negotiation Program "simply establishes maximum prices the Government will pay for selected drugs" that are dispensed, furnished, or administered to Medicare beneficiaries. *AstraZeneca*, 719 F. Supp. 3d at 396. It does not limit the price that non-beneficiaries pay, nor does it limit the price that a beneficiary pays if he chooses to obtain drugs without using his Medicare benefits (*i.e.*, pays cash). And because participation in Medicare and Medicaid is voluntary, the Negotiation Program does not enact a deprivation of any property.

It is well established that participation in Medicare and Medicaid "is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States,* 934 F.2d 719, 720 (6th Cir. 1991)); *see Baptist Hosp. E. v. HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d

1274, 1279-80 (11th Cir. 2014); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993).[21] Indeed, every district court to have addressed a Fifth Amendment challenge to the Negotiation Program has concluded that participation is voluntary. *See supra* at 7 (listing cases).

As those courts have explained, "[n]either the IRA nor any other federal law requires [manufacturers] to sell its drugs to Medicare beneficiaries." *AstraZeneca*, 719 F. Supp. 3d at 395-96; *see also, e.g.*, *Bristol Myers Squibb Co.*, 2024 WL 1855054, at *7 ("[T]he parties have not identified any authority holding that participation in the Medicare system is involuntary. The Court, despite diligent efforts, was likewise unable to identify any such authority." (citations omitted)). Manufacturers may choose not to sell their drugs to Medicare if they do not agree with the offered price. And the Negotiation Program applies only to entities that choose to participate in Medicare and Medicaid, and regulates only the prices the government will pay for certain drugs sold to Medicare beneficiaries. *See* Revised Guidance 120 ("[T]he IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation [in Medicare.]"); 26 U.S.C. § 5000D(c)(1) (making the applicability of the excise tax contingent on such participation). Thus, drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices need not do so. The Negotiation Program in no way alters the fact that a provider dissatisfied with the prices that Medicare offers "may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70.

To the extent Plaintiffs contend that the financial benefits of Medicare participation make withdrawal involuntary because it would impractical, "[c]ourts have roundly rejected such arguments." *Bristol Myers Squibb Co.*, 2024 WL 1855054, at *7 (collecting cases). Rather, "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Dayton Area Chamber of Com.,* 696 F. Supp. 3d at 456; *see also, e.g.*, *AstraZeneca*, 719 F. Supp. 3d at 396 (participation in Medicare "is a potential economic opportunity that [manufacturers are] free to accept or reject").

---

[21] Many of these cases address claims under the Takings Clause of the Fifth Amendment, rather than the Due Process Clause, but that context does not affect the conclusion that the economic incentive to participate in Medicare and Medicaid does not make such participation involuntary.

This is because practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis. *Garelick*, 987 F.2d at 917; *cf. St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Thus, even where "business realities" create a "strong financial inducement to participate" in a government program—*e.g.*, when Medicaid provides the vast majority of a nursing home's revenue—courts have uniformly held that participation "is nonetheless voluntary." *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986) ("[T]he fact that Medicare patients comprise a substantial percentage of [the plaintiffs'] practices does not render their participation 'involuntary.'"). Courts have likewise rejected the suggestion that participation in a voluntary program becomes involuntary if it may take some time to withdraw. *See Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (finding no violation of a protected property interest where a property owner could choose to leave a price-capped market with "6 or 12 months notice").[22]

Plaintiffs' reliance on *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), to argue otherwise is unavailing. In *NFIB*, the Supreme Court held that Congress's threat to withdraw all existing Medicaid funding from States was so coercive as to "violate[] the basic principle that the Federal Government may not compel the States to enact or administer a federal regulatory program." *Id.* at 575 (plurality opinion) (quotation marks and citation omitted). The Court explained

[22] While Plaintiffs claim to fear that withdrawal from Medicare might take 11 to 23 months, they ultimately acknowledge that CMS's guidance confirms that a manufacturer may withdraw in as little as 30 days. *See* Pls.' Br. at 30; *see also* Revised Guidance at 33-34 ("[A]ny manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue."). Plaintiffs suggest that the 30-day withdrawal notice is inconsistent with the statute, Pls.' Br. at 30, but Plaintiffs do not challenge that aspect of the Negotiation Program in this litigation. Regardless, Plaintiffs are incorrect. The Social Security Act provides that the relevant Medicare-participation agreements can be terminated by CMS in 30 days for "good cause." *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); *see also* Revised Guidance at 130 (relying on those statutory provisions to explain that if a "[m]anufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the . . . Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination in 30 days).

that the government could not threaten to withhold existing Medicaid funds as a means of "coerc[ing] a State to adopt a federal regulatory system as its own." *Id.* at 578. *NFIB*'s analysis thus addresses—and is derived exclusively from cases analyzing—how federalism principles inform what conditions Congress may attach to money it grants to States. *See id.* at 579-81 (plurality op.); *see also Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that the *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, . . . not a federal agency's ability to regulate [private] facilities' use of federal funding" (citation omitted)), *cert. denied*, 143 S. Ct. 294 (2022).

The same analysis does not apply when, rather than using grant conditions to "encourage a State to regulate in a particular way," *NFIB*, 567 U.S. at 576, the government uses its purchasing power to bargain with private sellers for lower drug prices. As explained above, *see supra* at 33-34, "no one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co.*, 616 F.2d at 342. Rather, it "has long been recognized that the government, like private individuals and businesses, has the power 'to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.'" *Ray Baillie Trash Hauling, Inc. v. Kleppe*, 477 F.2d 696, 709 (5th Cir. 1973) (quoting *Perkins*, 310 U.S. at 127). Any downward "pressure" on prices that Congress may exert through the terms of its procurement offers is analogous to the leverage of any well-funded market participant, which is of no constitutional import. Indeed, courts have continued to find participation in Medicare and Medicaid voluntary following *NFIB*. *See Se. Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014).

Plaintiffs have failed to establish that the Negotiation Program implicates any constitutionally protected interests of drug manufacturers, and Plaintiff PhRMA's due process claim fails.

B. Plaintiff NICA's due process claim lacks merit.

Plaintiffs next assert that the Negotiation Program deprives providers (such as those represented by NICA) of (1) their "interest in being reimbursed on a non-arbitrary basis at a lawful

rate" and (2) their investment in "building facilities and processes for administering Medicare-reimbursed drugs." Pls.' Br. at 25. This claim fares no better than PhRMA's.

Instead of explaining how the Negotiation Program implicates a constitutionally protected property interest, Plaintiffs simply restate their Article III standing arguments by arguing that "the selection of one of [NICA's] members' drugs will lead to a lower price for that drug." *Id.* at 24 (quoting *NICA*, 116 F.4th at 500-01). Although the Fifth Circuit held that these sorts of allegations sufficed to establish standing at the motion-to-dismiss stage, *see NICA*, 116 F.4th at 500-01, they do not establish a constitutional violation because providers have no protected interest in being reimbursed at their preferred levels. Rather, as explained above, *see supra* at 33-34, the government has the right "to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases,'" *AstraZeneca*, 719 F. Supp. 3d at 395 (emphasis omitted) (quoting *Perkins*, 310 U.S. at 127). And once again, Plaintiffs cite no authority entitling providers to compel the government to pay more for a good than it is willing to pay.

Plaintiffs' own cited authority confirms the lack of a property interest here. Both *Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 773-74 (7th Cir. 2021), and *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998), held only that Medicare and Medicaid providers have a property interest in reimbursement "at the legally prescribed rate," such as the amount due under a statutory formula, *Rock River Health Care*, 14 F.4th at 774, a preset fee schedule, *see Furlong*, 156 F.3d at 393, or a consistent pattern of administrative decisions interpreting a fee schedule, *see id.* at 395. Plaintiffs' preferred reimbursement totals are not "legally prescribed" in the same way. *Rock River Health Care*, 14 F.4th at 774. The only statutory, regulatory, or other legal authority Plaintiffs cite is the statutory reimbursement formula for Part B drugs, which Plaintiffs describe as "generally reflect[ing] the drug's 'average sales price' . . . plus a percentage (currently 6%)." Pls.' Br. at 5 (citing 42 U.S.C. § 1395w-3a); *see also* 42 U.S.C. § 1395w-3a(b)(1), (b)(3) (providing the reimbursement formula as "106 percent" of "the volume-weighted average of the average sales price"). But the Negotiation Program does not alter that statutory reimbursement formula; nor do Plaintiffs contend otherwise. *See NICA*, 116 F.4th at 500-01 (acknowledging that Plaintiffs' revenue may decrease, but only because the total amount

calculated under the reimbursement formula may decrease as a result of a lower market rate). Plaintiffs cite no authority for their alleged entitlement to have their *preferred* "average sales prices" inputted into that unchanged statutory formula. Indeed, in *Rock River Health Care*, the Seventh Circuit explicitly rejected the theory on which Plaintiffs rely here: that the providers were "entitled to a *particular* reimbursement rate" or "to whatever rate [the providers] believe is appropriate," divorced from any actual legal prescription. 14 F.4th at 774 (providers entitled only to the amount due under the legally proscribed "method of calculating the appropriate reimbursement rate," which formula was "strictly prescribed by the state law and administrative code").

Regardless, even accepting at face value Plaintiffs' view that "providers have a protected interest in being reimbursed on a non-arbitrary basis at a lawful rate," Pls.' Br. at 25, they will be. *See supra* at 4-5 (discussing criteria for CMS's offer price); Ex. 1, Buchmueller Decl. ¶¶ 11-14 (discussing leverage retained by manufacturers). The Negotiation Program thus passes even Plaintiffs' test.

Plaintiffs' assertion that the Negotiation Program deprives providers of their investment in "building facilities and processes for administering Medicare-reimbursed drugs," Pls.' Br. at 25, is even more tenuous. Even assuming Plaintiffs have a protected interest in their facilities and their administration processes, Plaintiffs make no attempt to explain how the Negotiation Program effects a deprivation of such interests. The Program does not seize providers' facilities or otherwise interfere with their "processes for administering Medicare-reimbursed drugs." *Id.* The IRA simply sets the terms of the government's offer to pay manufacturers for certain drugs. Providers have no right to force the government to pay manufacturers for those drugs on different terms. Plaintiffs have thus failed to establish that the Negotiation Program implicates any constitutionally protected interests of providers, and NICA's due process claim fails.

C. Plaintiff GCCA's due process claim lacks merit.

Finally, and most boldly, Plaintiffs state that the Negotiation Program violates the due process rights of Medicare and Medicaid patients (such as those represented by GCCA) because it may affect "whether existing products remain available to Medicare and Medicaid beneficiaries and whether future products are brought to market." *Id.* at 27. That is a policy argument (barely) masquerading as

constitutional law. Setting aside the question of whether any of Plaintiffs' policy critiques have merit, they cite no authority for the proposition that patients have a constitutional right to have all current Medicare and Medicaid products remain available through those programs forever—let alone some speculative right to the fruits of some possible future innovation. Within statutory bounds that are not challenged here, the government may decide what products and services it will pay for through Medicare and Medicaid. *See, e.g.*, *O'Bannon v. Town Ct. Nursing Ctr.*, 447 U.S. 773, 785 (1980) (explaining that 42 U.S.C. § 1396a(a)(23) confers on Medicaid recipients "the right to choose among a range of *qualified* providers, without government interference," but does not "limit the Government's right to . . . decertify[] a facility").

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion for summary judgment, dismiss Plaintiffs' excise-tax claim for lack of subject-matter jurisdiction, and enter summary judgment for Defendants on all remaining claims.

Date: April 21, 2025

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General
Civil Division

MARGARET LEACHMAN
Acting United States Attorney

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Stephen M. Pezzi
STEPHEN M. PEZZI
Senior Trial Counsel
CASSANDRA M. SNYDER
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
(202) 305-8576
stephen.pezzi@usdoj.govov

Counsel for Defendants